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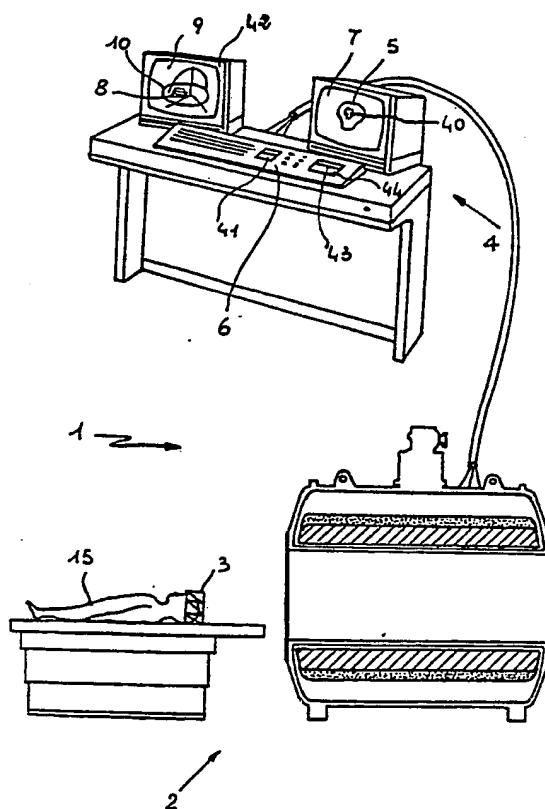
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<p>(21) International Application Number: PCT/EP89/01362</p> <p>(22) International Filing Date: 14 November 1989 (14.11.89)</p> <p>(30) Priority data: 22659 A/88 18 November 1988 (18.11.88) IT</p> <p>(71) Applicant (for all designated States except US): ISTITUTO NEUROLOGICO "CARLO BESTA" [IT/IT]; Via Celoria, 11, I-20133 Milano (IT).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): GIORGI, Cesare [IT/IT]; Foro Buonaparte, 53, I-20100 Milano (IT).</p> <p>(74) Agent: RAPISARDI, Mariacristina; Studio Tecnico Legale Rapisardi, Largo V Alpini, 15, I-20145 Milano (IT).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), BR, CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: PROCESS AND APPARATUS PARTICULARLY FOR GUIDING NEUROSURGICAL OPERATIONS

(57) Abstract

The process for guiding neurosurgical operations allows to considerably reduce surgical traumatism during the removal of cerebral lesions by virtue of the possibility of converting into three-dimensional images both the contours of the anatomical structures and the representation of the device for the stereotaxic detection of the affected region together with a stereotaxic probe which defines a surgical path. The apparatus for executing the above mentioned process comprises means (4) for transferring two-dimensional radiological images (5) arriving from a CAT or MR device to a computer (6) which is equipped with a visual display and comprises processing means for converting the two-dimensional images into three-dimensional images (8) together with the schematic three-dimensional representation of the stereotaxic detection device (3).



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PROCESS AND APPARATUS PARTICULARLY FOR GUIDING
NEUROSURGICAL OPERATIONS

TECHNICAL FIELD

The present invention relates to a process and
5 apparatus particularly for guiding neurosurgical
operations.

BACKGROUND ART

As is known, neuroradiological diagnostics has
currently undergone an enormous development, especially
10 with the introduction and use of devices such as CAT
(computerized axial tomography) and MR (magnetic
resonance) which can provide the surgeon with anatomical
information in order to allow him to reach the lesion on
the patient especially in the case of some kinds of
15 endocranial lesions.

For these and other reasons, stereotaxic
neurosurgical technique has developed considerably, since
the execution of neuroradiological examinations in
stereotaxic conditions allows to give each element of the
20 radiographic image a precise orientation with respect to a
preset operative reference system.

Such systems are mainly used especially with regard
to cerebral lesions, but this does not mean that in the
near future, with the development in the field of
25 neurosurgical armamentarium, such systems might not be
used effectively on any part of the human body.

Reference is therefore hereinafter made to
neurosurgical operations, bearing in mind the non-
limitation of use of the process according to the
30 invention only to such operations.

In the case of cerebral lesions, since the encephalon is not subjected to significant modifications with respect to the braincase from the time of execution of the radiological examinations to the time of surgical intervention, it is possible to study and develop various possibilities of neurosurgical execution based on the different stereotaxic paths of approach to the cerebral lesions which the surgeon intends to use, according to the neuro-anatomical information acquired, as mentioned, by CAT or MR.

The use of CAT or MR currently allows to determine the coordinates of a lesion or of a neoplasm identified on the planar radiological image and therefore to determine the angles which define the so-called approach path, i.e. the preferred and best, though sometimes longer, direction followed by the surgeon during the actual operation.

The definition of the approach path with regard to the radiological image is currently generally performed by the surgeon at the diagnostic console with which the CAT or MR device is equipped.

By examining the various radiological images in succession (as regards CAT, by viewing in succession biplanar anatomical sections of the parallel sections or, as regards MR, by examining the semiaxial, frontal or sagittal planes), the surgeon must visualize the three-dimensional extension of the anatomical elements shown in the radiological images and therefore decide on the basis of his experience the surgical path to be followed during the operation so as to not damage the tissues adjacent to the lesion.

By means of this procedural method, which is currently in use, the surgeon is able to locate and reach with sufficient precision any neoplasm or part of the encephalon, but can never have such information as to
5 allow him to plan the operation with absolute certainty.

This disadvantage arises from the fact that the axis of the path of the surgical probe which traverses the various anatomical elements in order to reach the lesion is not, in most cases, along one of the planes defined by
10 the parallel sections of the CAT radiographs or of the semiaxial, frontal or sagittal planes of MR in which the anatomical image is represented.

This is why the three-dimensional reconstruction of the image is totally left to the visualization ability of
15 the surgeon.

The surgeon therefore currently chooses a path of approach to the neoplasm by examining in succession the various sections provided by CAT and MR, but is unable to examine the complete volume of the lesion.

20 The problem becomes more severe if, for example, the purpose of the intervention is to place a pellet of a radioactive isotope for a curative treatment inside the lesion or if said lesion is to be removed.

Especially in such cases, but also in the case in
25 which a simple bioptic sampling must be performed, with the current method it is difficult for the surgeon to be perfectly aware of the various interconnections occurring between the lesion and the healthy cerebral structures which surround it.

30 The difficulty of determining a theoretical path to

be followed during the operation in order to reach the required point of the lesion by examining in succession the various biplanar anatomical sections resulting from the images produced by CAT or MR is consequently
5 imaginable.

In addition to the above, it is furthermore stressed that the various determinations of the anatomical data performed on different devices cannot be integrated into a single image since they are presented separate from one
10 another on the different consoles of the devices which produced them.

By way of example, the known art does not allow to evaluate the information supplied by angiography, an examination of extreme diagnostic significance,
15 simultaneously with the images provided by CAT or by MR, since the three-dimensional visualization of the cerebral vessels is not possible.

It is therefore practically impossible to determine the possible collision of a surgical path with the
20 vascular structures.

DISCLOSURE OF THE INVENTION

The aim of the present invention is to eliminate the above described disadvantages by providing a process and an apparatus particularly for guiding neurosurgical
25 operations which allow to considerably reduce surgical traumatism during the removal of lesions, for example cerebral ones, using stereotaxic methods guided by the anatomical reconstruction of images arriving from CAT or MR.

30 Within the scope of this aim, an important object of

the invention is to provide a process and apparatus particularly for guiding neurosurgical operations which allow to adopt surgical approach paths which avoid traumatism of the healthy tissue which surrounds even deep
5 lesions by performing a surgical path which may sometimes be longer than what normally occurs for lesions proximate to the convexity of the braincase.

Another object of the present invention is to provide a process and apparatus particularly for guiding
10 neurosurgical operations which allow to visualize in three dimensions, together with the lesion, the cerebral structures of surgical interest, especially the main vessels, the internal capsule and the nuclei, as well as the eloquent cortical regions.

15 Not least object of the present invention is to provide a process and apparatus particularly for guiding neurosurgical operations which allow to provide information on the orientation of the surgical instruments relative to the operative reference.

20 This aim, these objects and others are substantially achieved by a process and apparatus particularly for guiding neurosurgical operations, characterized in that it consists in: performing the required neuroradiological examinations, by means of at least one stereotaxic
25 detection device, on a part of the patient; loading in the memory of a computer the radiological images arriving from a computerized axial tomography device or from a nuclear magnetic resonance device; storing in said computer the location of the reference points produced by said
30 stereotaxic detection device on said radiological images;

detecting in said computer the contour of the different anatomical structures of each of said images; storing in said computer said contour of said different anatomical structures; processing, by means of a specific program, all the data entered into said computer to represent on a visual display a schematic three-dimensional image of said contours of said different anatomical structures of said images together with a schematic three-dimensional image of said stereotaxic detection device and of a stereotaxic probe which defines a surgical path.

Said process is performed by an apparatus particularly for guiding neurosurgical operations, comprising a computerized axial tomography device or a magnetic resonance device connected to a stereotaxic detection device, characterized in that it comprises: means for transferring two-dimensional radiological images arriving from said computerized axial tomograph device or from said magnetic resonance device to a computer equipped with a visual display, said computer comprising processing means for converting said two-dimensional radiological images into three-dimensional images on said visual display simultaneously with the schematic three-dimensional representation of said stereotaxic detection device.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the invention will become apparent from the description of a preferred but not exclusive embodiment of a process and apparatus particularly for guiding neurosurgical operations according to the invention, illustrated only by

way of non-limitative example in the accompanying drawings, wherein:

figure 1 is a schematic perspective view of the apparatus for guiding neurosurgical operations according to the invention;

figure 2 is a block diagram of the apparatus illustrated in figure 1;

figure 3 is an enlarged view of the three-dimensional image which is displayed on the visual display of the apparatus according to the invention;

figure 4 is a perspective view of the locator device according to the invention;

figure 5 is a schematic view of the projection of the reference points of the locator device on a stereoscopic projection obtained with a digital angiograph;

figure 6 is a view of the stereotaxic probe superimposed on two stereoscopic angiographic images; and

figure 7 is a schematic view of the articulated arm adapted to place the anatomical three-dimensional images in a univocal spatial relationship with the orientation of one or more surgical instruments.

WAYS OF CARRYING OUT THE INVENTION

With reference to the above described figures, the process according to the invention is provided by means of the following succession of steps.

A stereotaxic detection device, more precisely a stereotaxic helmet (3), is initially fitted onto the patient (15) in order to subject him to the preparatory neuroradiological examinations before surgery.

The stereotaxic helmet comprises a locator element

(16) by means of which it is possible to detect and identify the arrangement of the plane of the image in relation to the operative reference constituted by said stereotaxic helmet.

5 The use of stereotaxic helmets made of a material suitable for being shown by neuroradiological examinations without distorting or masking the image, conveniently allows to univocally and precisely determine a plurality of references, and it is possible to determine the
10 position of the plane of the radiological image according to the positioning of said references.

 The radiographic images thus obtained by MR or CAT, by means of the use of the stereotaxic helmet, are fed into the computer (6) and loaded into memory to be then
15 displayed on the display of said computer.

 Once the computer has acquired the arrangement of the sectional plane of each radiographic image arriving from CAT or MR, the operator, and more precisely the surgeon, can trace the contour of the anatomical structures (40)
20 which occur on each section and are, in his opinion, relevant for the planning of the operation.

 The limits of the pathological tissue, the position of the ventricles, the main vessels and the eloquent cerebral areas are generally determined.

25 This detection of the contour of the anatomical structures occurring in each radiographic image is performed for example manually by the surgeon, using a cursor driven by a digitizer pad (43), naturally after the specifications of the type of stereotaxic helmet used for
30 the detection of the neuroradiological tests performed on

CAT or on MR has been fed into the computer.

5 The above described procedure is repeated by the surgeon for each radiological image of CAT or MR, and an identical color is assigned to the contours which belong to the anatomical structure related to a same kind of tissue, so as to facilitate the identification of the various tissues even if they mutually interpenetrate.

10 When all the information has been acquired by the computer, the computer is capable, by means of a particular program, of displaying on the display a three-dimensional schematic image of the stereotaxic helmet and of a stereotaxic probe 21 which defines the surgical path chosen by the surgeon to perform the actual operation.

15 The various contours of the anatomical structures of the radiological images, which had been previously determined by the surgeon, as previously specified, are simultaneously reproduced in three dimensions inside the diagram defined by the schematic representation of the stereotaxic helmet, and areas intended to control the rotation of the image and the orientation of the stereotaxic probe are displayed in the peripheral part of the visual display.

20 Finally, the angle (42) and depth values, which correspond, on the helmet used during surgery, to the path defined by the stereotaxic probe chosen by the surgeon on the visual display for the approach to the operation, are also indicated on the visual display.

25 In an alternative solution, an articulated arm, indicated by 30, having at least six degrees of freedom and position detectors 31 associated with the regions

30

where its configuration changes, can be used to give the computer the orientation of the arm with respect to the stereotaxic helmet 3 with which said arm is associated in a preset manner by means of the feet 32.

5 By means of the articulated arm it is possible to arrange the three-dimensional anatomical images 8 in univocal spatial relationship with the orientation of one or more known surgical instruments, not illustrated in the drawings, which are orientated by the surgeon during the operation.

10 More in detail, the articulated arm is rotatably associated with an annular base plate 33 which, as already mentioned, is associated with the stereotaxic helmet 3 by means of the feet 32.

15 The first rod-like element 34 of the arm is telescopingly extendable and rotatably supports a second rod-like element 35 which is also telescopingly extendable and in turn articulately supports a third rod-like element 36 adapted to receive on its free end one or more surgical instruments.

20 As regards the conversion of the cerebral angiographic radiological images into three-dimensional images, the process according to the invention is performed according to the following succession of steps.

25 The stereotaxic helmet, arranged in the identical position in which CAT and MR were performed, is initially positioned so that it is in the isocenter of rotation of the cathode-ray tube of a conventional digital angiograph.

30 In this manner a series of image acquisitions is performed according to defined stereoscopic projections.

5 A locator device 16 is furthermore associated with the stereotaxic helmet and comprises a ring 20 from which three rods 17 extend perpendicular to the plane of said ring, each of said rods being tipped by a small steel sphere 18.

10 The three rods are conveniently spaced from one another on the perimeter of the ring and have a mutually different height from the plane of the helmet, so as to not mutually superimpose in the different angles and project images in different positions on the stereoscopic angiographic sequences illustrated in figures 5 and 6.

In a preferred technical solution, the images thus obtained are digitized by means of a TV camera and transferred to the surgical graphic computer.

15 At this point the surgeon, using the cursor of a digitizer pad, can identify in each image the exact position of the three spheres and therefore the angle of acquisition of the angiographic image.

20 By virtue of the above, since the distances between the focus of the cathode-ray tube, the stereotaxic helmet and the plane of the image and obviously the arrangement of the stereotaxic helmet in the plane of rotation of the cathode-ray tube of the digital angiograph are fixed and known, it is possible to univocally determine the angle of acquisition of each angiographic projection.

25 At this stage it is possible, by means of the computer, to calculate the projection of a stereotaxic path in relation to each angle of acquisition of each angiographic projection and thus superimpose it on each of the stereotaxically acquired angiographic images.

30

At this point the surgeon can determine the optimum surgical path by using the information detected by CAT or MR and obtain the projection of the chosen path 21 on the stereotaxically acquired angiographic images.

5 From what has been described, the simultaneous observation of two stereoscopic images, by means of appropriate glasses, allows the three-dimensional perception of the mutual relationships between the vascular structures and the surgical probe.

10 Obviously, if the surgical target is a vascular structure, the entire planning of the operation will be performed exclusively on the angiographic images.

As previously mentioned, the apparatus for guiding neurosurgical operations, generally indicated by the reference numeral 1, comprises a computerized axial tomography device or, as illustrated in figure 1, a magnetic resonance device 2 connected to a stereotaxic detection device, such as a known stereotaxic helmet 3 worn by a patient 15.

20 The apparatus 1 comprises means 4 for transferring the two-dimensional radiological images 5, arriving for example from the MR, to a computer 6 equipped with a visual display 7.

25 The computer 6 comprises in turn processing means, and more in detail software adapted to convert the two-dimensional images 5 into three-dimensional images 8 which are visible on a visual display 9 together with the three-dimensional schematic representation 10 of the stereotaxic helmet.

30 The apparatus for performing the three-dimensional

processing of the cerebral angiographic images comprises a known digital angiograph, not illustrated in the drawings, in which the stereotaxic helmet 3 worn by the patient 15 is placed exactly at the isocenter of rotation of the cathode-ray tube.

A locator device 16 can furthermore be removably associated on the stereotaxic helmet and has three rods 17 tipped by small steel spheres 18 which are appropriately spaced and mounted at a different height from the plane of the helmet.

The invention thus conceived is susceptible to numerous modifications and variations, all of which are within the scope of the inventive concept; all the details may furthermore be replaced with technically equivalent elements.

In practice, the materials employed, as well as the dimensions, may be any according to the requirements and to the state of the art.

CLAIMS

- 3 1. Process particularly for guiding neurosurgical
4 operations, characterized in that it consists in:
5 performing the required neuroradiological examinations by
6 means of at least one stereotaxic detection device (3) on
7 a part of a patient (15); loading in the memory of a
8 computer (6) the radiological images (5) arriving from a
9 computerized axial tomography device and/or from a nuclear
10 magnetic resonance device; storing in said computer the
11 location of the reference points (18) produced by said
12 stereotaxic detection device on said radiological images;
13 detecting in said computer the contour of the different
14 anatomical structures (40) of each of said images; storing
15 in said computer said contour of said different anatomical
16 structures; processing, by means of a specific program,
17 all the data entered into said computer in order to
18 represent on a visual display (9) a schematic three-
19 dimensional image (8) of said contours of said different
20 anatomical structures of said images together with a
21 schematic three-dimensional image (10) of said stereotaxic
22 detection device and of a stereotaxic probe (21) which
23 defines a surgical path.
- 24 2. Process according to claim 1, characterized in
25 that said computer is accommodated in the immediate
26 neighborhood of the operating room where the surgical
27 operation is performed on said patient.
- 28 3. Process according to claim 1, characterized in
29 that said stereotaxic detection device (3) comprises a
30 locator element (16) for detecting the position of at

1 least one surgical instrument relative to said
2 radiological images in relation to said stereotaxic
3 detection device.

4 4. Process according to claim 3, characterized in
5 that said locator element comprises an articulated arm
6 (30) which is rotatably associated with an annular base
7 plate (33) which has feet (32) for associating it with
8 said stereotaxic detection device (3) in a preset manner.

9 5. Process according to claim 4, characterized in
10 that said articulated arm has a first rod-like element
11 (34) which is rotatably associated with a second rod-like
12 element (35) which in turn rotatably supports a third rod-
13 like element (36) for supporting surgical instruments,
14 said arm having position detectors (31) associated with
15 the regions in which its configuration varies.

16 6. Process according to claim 5, characterized in
17 that at least one of said first and second rod-like
18 elements is telescopingly extendable.

19 7. Process according to claim 1, characterized in
20 that the storage of said contour of said different
21 anatomical structures, arriving from said computerized
22 axial tomography device and/or from said nuclear magnetic
23 detection device, in said computer is performed manually
24 by moving a cursor (43) on a digitizer pad (44).

25 8. Process according to claim 1, characterized in
26 that said contour of said different anatomical structures
27 of said radiological images has an identical coloring for
28 each kind of tissue.

29 9. Process according to claim 1, characterized in
30 that said visual display has control means (41) for

1 rotating said first three-dimensional image and for
2 orientating said surgical path relatively thereto.

3 10. Process according to claim 1, characterized in
4 that said visual display has indications of angle values
5 (42) and of the depth of said surgical path which
6 correspond to equivalent angular values of an operative
7 guiding device.

8 11. Apparatus particularly for guiding neurosurgical
9 operations, comprising a computerized axial tomography
10 device or a magnetic resonance device (2) connected to a
11 stereotaxic detection device (3), characterized in that it
12 comprises means (4) for transferring two-dimensional
13 radiological images (5) arriving from said computerized
14 axial tomography device or from said magnetic resonance
15 device to a computer (6) equipped with a visual display
16 (9), said computer comprising processing means for
17 converting said two-dimensional radiological images into
18 three-dimensional images (8) on said visual display (9)
19 and for the schematic three-dimensional representation of
20 said stereotaxic detection device.

21 12. Apparatus according to claim 11, characterized in
22 that it comprises a digitizer pad (43) for interaction
23 with said three-dimensional images on the part of an
24 operator.

25 13. Process particularly for guiding neurosurgical
26 operations, characterized in that it consists in: applying
27 a stereotaxic helmet (3) on a patient; associating with
28 said stereotaxic helmet a locator device (16); performing
29 a series of stereotaxic acquisitions according to
30 stereoscopic projections defined by means of a digital

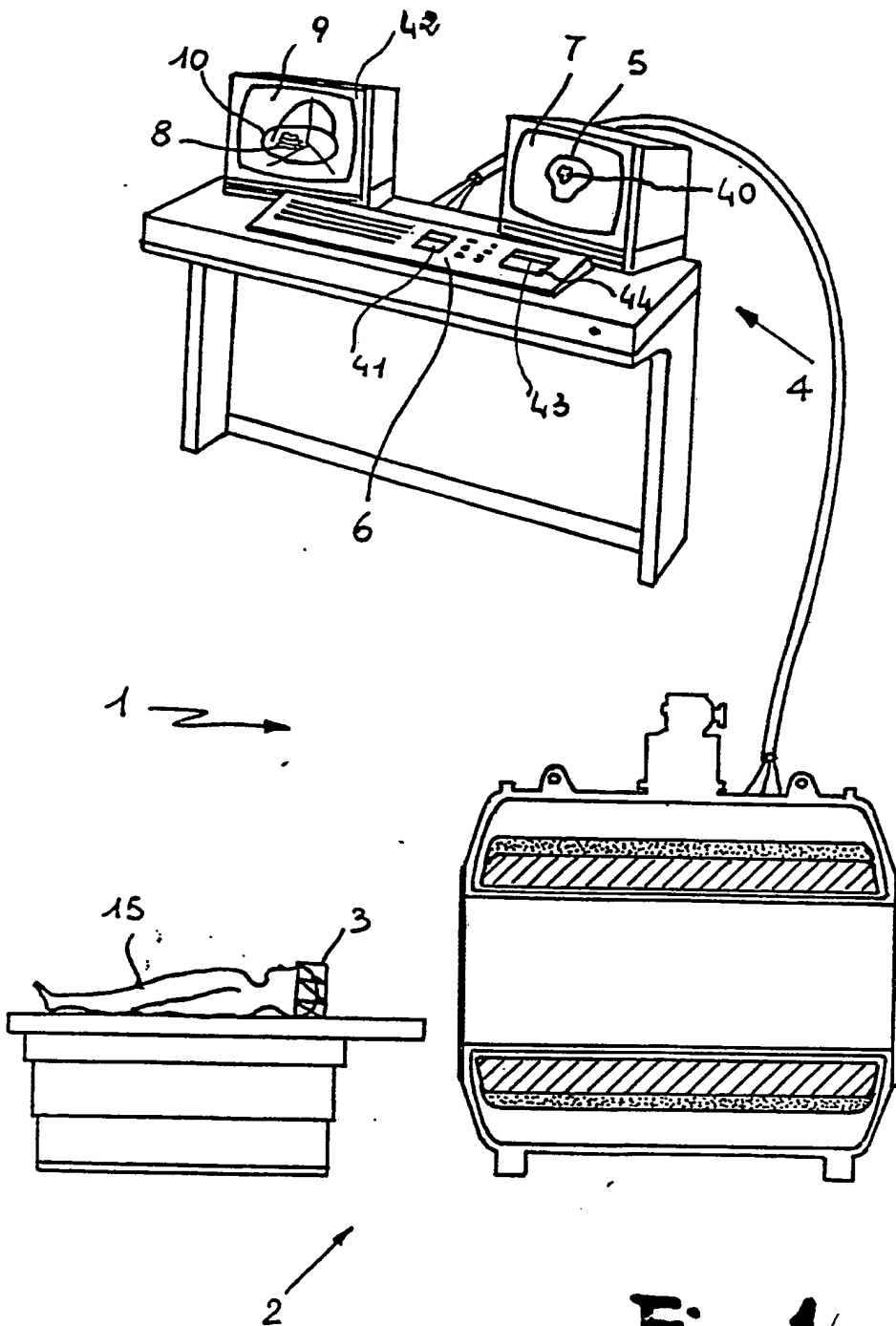
1 angiograph; projecting onto each of said stereoscopic
2 projections a plurality of reference points (18) of said
3 locator device; storing said stereotaxic acquisitions in a
4 computer (6); identifying said reference points in each
5 stereoscopic angiographic image; univocally determining
6 the angle of acquisition of each angiographic projection;
7 calculating the projection of a stereotaxic path for each
8 of said acquisition angles; superimposing said projection
9 onto said angiographic image.

10 14. Process according to claim 13, characterized in
11 that said stereotaxic helmet and said locator device are
12 arranged in the isocenter of rotation of the cathode-ray
13 tube of said digital angiograph.

14 15. Process according to claim 13, characterized in
15 that said locator device comprises an annular element (20)
16 from which at least three rods (17) extend
17 perpendicularly, each rod having a sphere (18) at its end.

18 16. Process according to claim 13, characterized in
19 that said rods are mutually spaced along the perimeter of
20 said ring and have mutually different heights.

21 17. Process and apparatus particularly for guiding
22 neurosurgical operations, characterized in that they
23 comprise one or more of the described and/or illustrated
24 characteristics.

**Fig. 1**

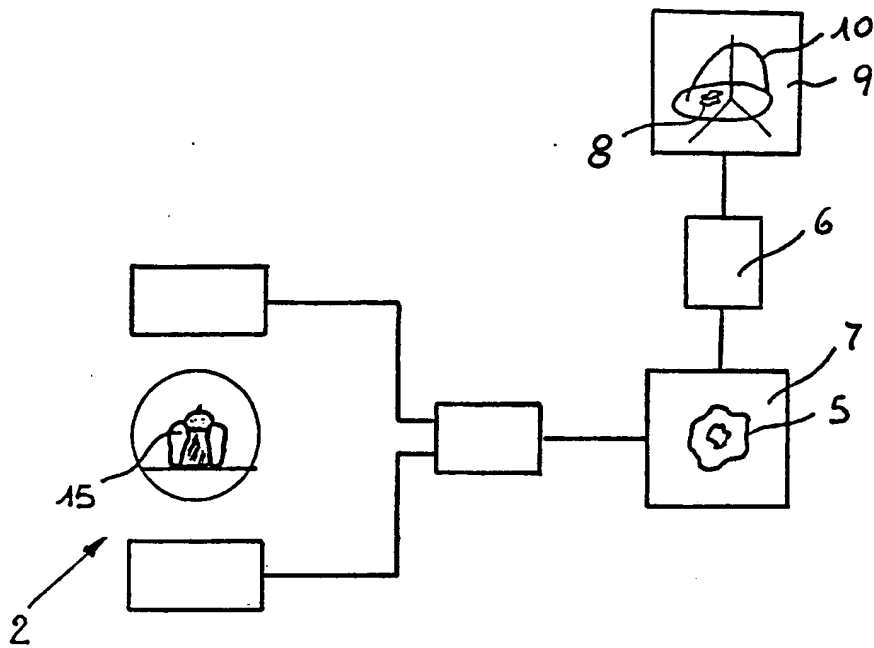


Fig. 2

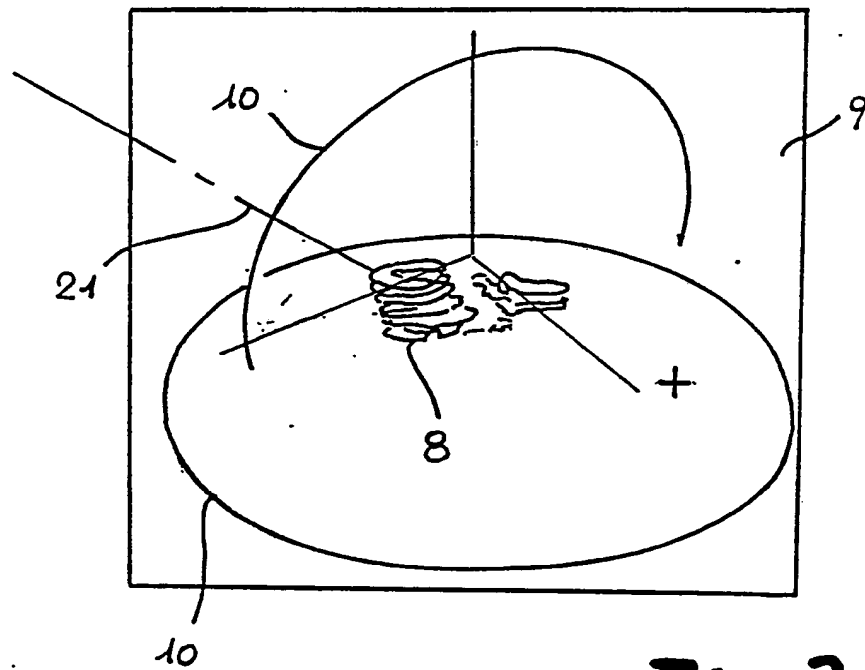


Fig. 3

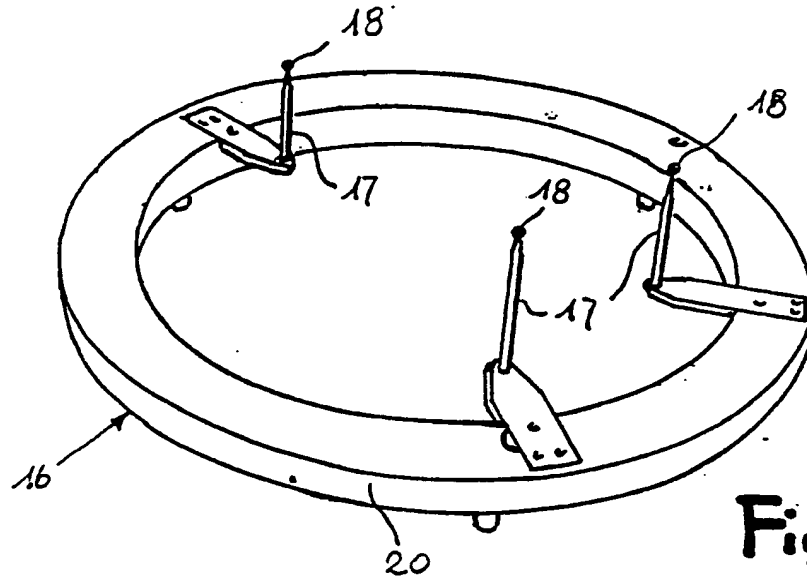


Fig. 4

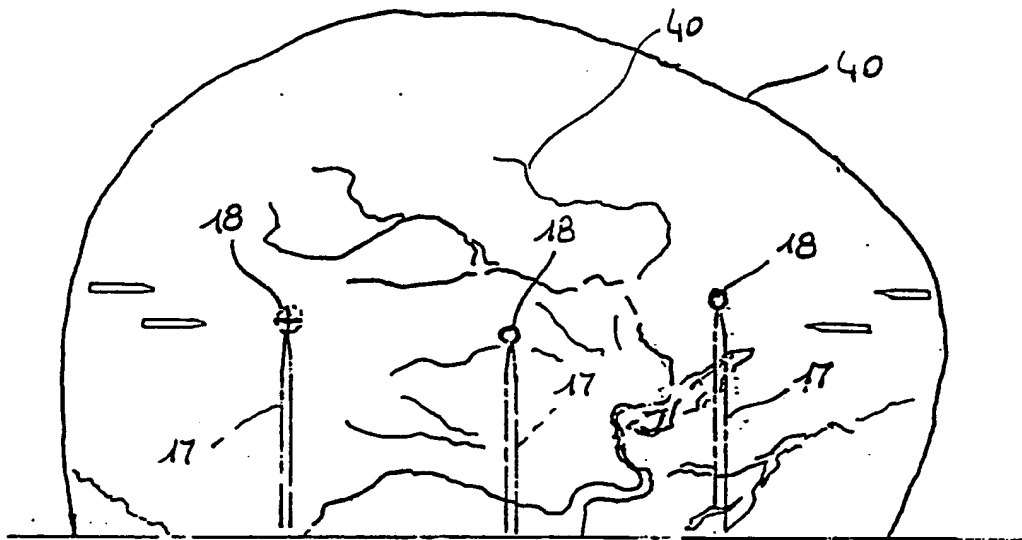


Fig. 5

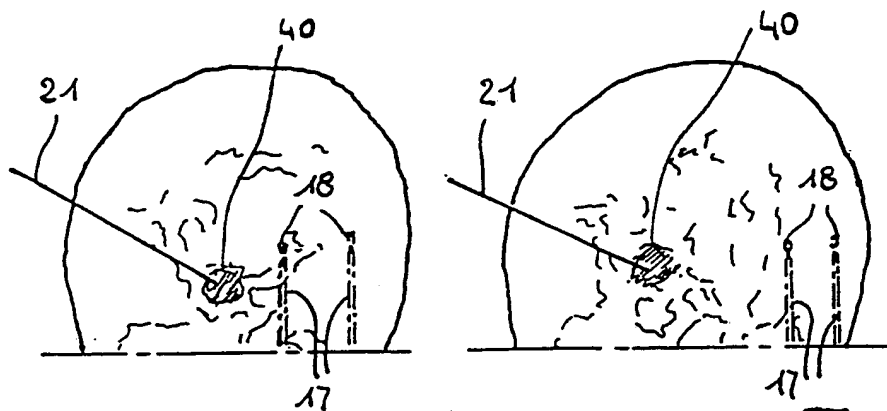
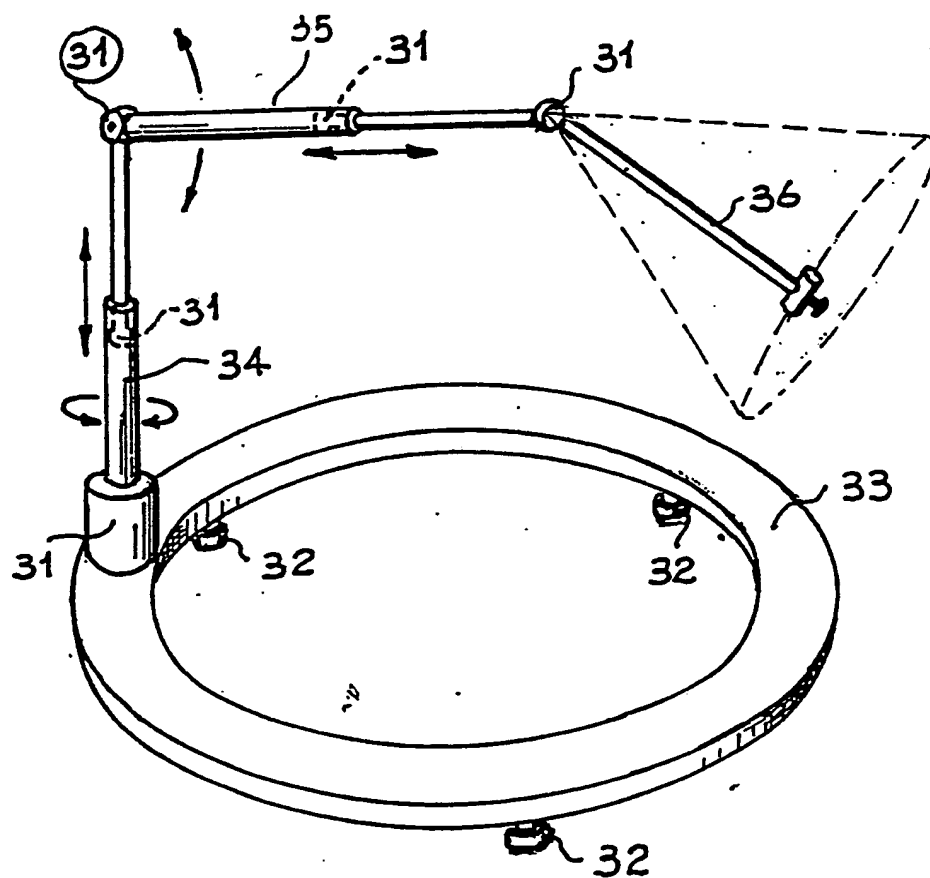


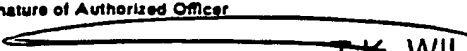
Fig. 6

**Fig. 7**

INTERNATIONAL SEARCH REPORT

International Application No. PCT/EP 89/01362

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 B 19/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System :	Classification Symbols	
IPC ⁵	A 61 B	
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III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4638798 (SHELDEN et al.) 27 January 1987 see column 4, line 64 - column 5, line 15; column 6, lines 13-35; column 7, lines 42-50; column 9, lines 33-50; column 12, lines 28-35; figures 3,4,9	1-3,7-17
A	US, A, 4465069 (BARBIER et al.) 14 August 1984 see column 5, lines 5-20; figure 1	3-6

<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
8th March 1990	12. 04. 90	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	 T.K. WILLIS	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

EP 8901362

SA 32234

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 03/04/90. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4638798	27-01-87	None	
US-A- 4465069	14-08-84	None	